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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/283,645 04/01/99 KHETANI

V CELG-0119

HM12/0125

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EXAMINER

CHANG, C

ART UNIT

PAPER NUMBER

1625

DATE MAILED:

01/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/283,645

Applicant(s)
Khetani et al.

Examiner
Celia Chang

Group Art Unit
1625



☒ Responsive to communication(s) filed on Dec 28, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-8, 10-13, and 15 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) 1-8, 10-13, and 15 is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. This application is a RCA of S.N. 08/283,645. Claims 1-8, 10-13 and newly added claim 15 are pending.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Jursic et al.

Jursic et al. disclosed process of the claims, i.e. the exact compound in the enantiomeric forms, the acidic resolving agents (see p.1712-1713 structure and acidic functionality), and the salt complex (see p.1713 the complex of the acidic resolving agent and the amide compound is the formation of hydrogen bonding, Acidic----H---N---base, i.e. an amine salt).

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8, 10-11, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jursic et al. in view of Berrang et al. CA 97; Ohashi et al. CA 104; or Vanderplas et al. CA 118.

Jursic et al. disclosed process of separating enantiomeric isomers of the claims by formation of the racemic compounds with a chiral resolving agent (see p 1712-1713) in an organic solvent (see p 1713). The difference between the claims and ~~Berrang~~ ^{Jursic} is that instead of the chiral resolving agents disclosed on p.1712, applicants used an alternative conventional chiral resolving

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agent. The well recognition of the claimed chiral resolving agents are found in Berrang et al., Ohashi et al. or Vanderplas et al. wherein enantiomeric amino compounds are resolved into stereo isomeric forms through formation of a stereo specific complex between the compounds and the chiral agent. One having ordinary skill in the art would be motivated to employ these conventional chiral resolving agents for separation of enantiomers knowing that such isomers have been separated with alternative chiral agents as disclosed by ~~Branko~~ ^{Jursic}.

Further, in so employing the conventional chiral resolving agents of the claims, a salt complex between the compound and the chiral agent, i.e. product of claim 13, is expected to form since it was taught by ~~Branko~~ ^{Jursic} that such amine salt complex formation is through hydrogen bonding (p.1714).

Applicants argued that the difference of amide containing resolving agent of Jursic et al. would not motivate one skilled in the art to choose an alternative "acid" resolving agent. This is not persuasive because not only Jursic explicitly taught that the amides are acidic in function but also it is well recognized in the art that choosing an optical resolving agent is in its recognition of optical property. The well recognized tartaric acid as claimed is analogous to its amide i.e. the tartranilic acid (see US4,410,700 col.9, lines 41-42 and structural delineation of tartranilic acid) being acidic optical resolving agent. Therefore, artisan having ordinary skill in the optical resolution field would find that operability of the resolving agent disclosed by Jursic would motivate the picking and choosing of alternative resolving agent with expectation of reasonable success in separation of enantiomers.

4. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jursic et al. In view of Berrang et al. CA 97; Ohashi et al. CA 104; or Vanderplas et al. CA 118 further in view of Patrick et al.

The finding of prima facie obviousness over ~~Branko~~ ^{Jursic} in view of Berrang, Ohashi or Vanderplas as delineated supra is also applicable here and incorporated here by reference. The

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instant claim 12 differs from the ^{Juric}~~Branke~~ process in that an additional step for making the compounds from a pyridinyl precursor was incorporated. This precursor addition is also an conventional step in preparation of the claimed compounds as disclosed by Patrick (see p.487). Therefore, one having ordinary skill in the art who is well aware of all the pertinent art in the field, would be motivated to start the preparation from an alternative readily available precursor material as taught by Patrick with reasonable expectation of success.

5. Claims 1-8, 10-13 and 15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,936,091.

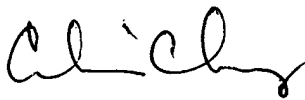
Although the conflicting claims are not identical, they are not patentably distinct from each other because the generic claims of the instant application included the patented claims and no acceptable terminal disclaimer has been filed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is (703) 308-4702.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

CCC/Chang

Jan. 17, 2001


CELIA CHANG
PRIMARY EXAMINER
GROUP 1200 16 25